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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,880	01/17/2006	Young Shin Song	4240-140	2148

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER	
JOIKE, MICHELE K	

ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,880	SONG ET AL.	
	Examiner	Art Unit	
	MICHELE K. JOIKE	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

As requested by Applicants in their January 31, 2008 response, the January 9, 2008 restriction requirement made by the previous examiner has been withdrawn, and a new restriction requirement with the current set of pending claims is made. The Examiner apologizes for any inconvenience.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4,8,10-13, 14, 23-25 drawn to a plasmid wherein two restriction enzyme recognition sites into which a T-vector can be cloned are introduced at the downstream of a promoter of a vector that is constantly expressed at high levels regardless of the kind of a host cell, whereby the plasmid functions as both the T-vector and an expression vector, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganisms containing the expression vector.

Group II, claim(s) 5-6, 9, 19-22, drawn to a pHCE-FOREX plasmid functioning as both a T-vector and an expression vector, wherein two AspEI restriction enzyme recognition sites are introduced at the downstream of the HCE promoter of the pPHC vector, and a polynucleotide having AspEI restriction enzyme recognition sites at its both ends is inserted between the two AspEI restriction enzyme recognition sites, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganisms containing the expression vector.

Group III, claim(s) claim 7, drawn to methods of making a pHCE-FOREX plasmid function as both a T-vector and an expression vector.

Group IV, claim(s) 15, drawn to an expression vector library, prepared by the method comprising the steps of: (a) removing the inserted polynucleotide by digesting the plasmid of claim 2 with the restriction enzyme selected from the group consisting of HphI, MboII, AspEI, and XcmI; and (b) inserting the library of various genes into a position from which the polynucleotide was removed.

Group V, claim(s) 16, drawn to an expression vector library wherein the library of various genes is inserted in the pHCE-FOREX-T vector.

Group VI, claim(s) 17-18 (in part), drawn to method of determining the cloning of a target gene, comprising the transformation of microorganisms with the libraries of claim 15.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the claims inventions lack novelty. Jo et al (A Simple Method to construct T-vectors Using XcmI Cassettes Amplifies by Nonspecific PCR, Plasmid, 2001. 45:37-40) teaches the development of a T-vector capable of functional as an expression vector, pNB-T (see abstract). The pNB-T vector was used to PCR clone a reporter gene GAPDH, using the XcmI sites, and then transformed into E. coli (see page 38, and Figure 2). Thus Jo et al teaches the claimed invention. *Note: the Examiner is not attaching a copy of this reference since it was mailed to Applicants with the previous restriction requirement.

The technical feature of group I, drawn to a plasmid wherein two restriction enzyme recognition sites into which a T-vector can be cloned are introduced downstream of a promoter of a vector that is constantly expressed at high levels regardless of the kind of a host cell, whereby the plasmid functions as both the T-vector and an expression vector, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganisms containing the expression vector, is distinct from the technical feature of group II, drawn to a pHCE-FOREX plasmid functioning as bother a T-vector and an expression vector, wherein two AspEI restriction enzyme recognition sites are introduced at the downstream of the HCE promoter of the pHCE vector, and a polynucleotide having AspEI restriction enzyme recognition sites at its both ends is inserted between the two AspEI restriction enzyme recognition sites, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganisms containing the expression vector. The T-vector of group I does not require the pHCE-FOREX vector of group II. Additionally, the pHCE-FORCE vector of group II, requires the use of AspEI sites, which are not required in group I. Thus group I and II are biologically, compositionally and biologically distinct and are capable of supporting individual patents.

The technical feature of group I, drawn to a plasmid wherein two restriction enzyme recognition sites into which a T-vector can be cloned are introduced at the

downstream of a promoter of a vector that is constantly expressed at high levels regardless of the kind of a host cell, whereby the plasmid functions as both the T-vector and an expression vector, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganisms containing the expression vector, is distinct from the technical feature of group III, drawn to methods of making a pHCE-FOREX plasmid function as both a T-vector and an expression vector. The composition of group I, does not require the pHCE-vector of group III, and group I can be made using alternate methodologies and reagents that those in group III. Additionally, the technical feature of group III, drawn to methods of making a pHCE vector, doe not require the vectors of group I. Additionally, group I is drawn to a composition, and group III is drawn to a method of making a distinct composition that that of group I. Thus group I and III are biologically, compositionally and biologically distinct and are capable of supporting individual patents.

The technical feature of group I, drawn to a plasmid wherein two restriction enzyme recognition sites into which a T-vector can be cloned are introduced at the downstream of a promoter of a vector that is constantly expressed at high levels regardless of the kind of a host cell, whereby the plasmid functions as both the T-vector and an expression vector, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganisms containing the expression vector, is distinct from the technical feature of group IV, drawn to an expression vector library, prepared by the method comprising the steps of: (a) removing the inserted polynucleotide by digesting the plasmid of claim 2 with the restriction enzyme selected from the group consisting of HphI, MboII, Asp EI, and XcmI; and (b) inserting the library of various genes into a position from which the polynucleotide was removed. The technical feature of group I does not require the library of group IV, and the vectors of group I can be used for alternate compositions, other than an library, such as to generate a transgenic animal, as probe for an immunoblot, or for the production of a recombinant protein. The technical feature of group IV, drawn to an expression library of vector requires various target genes, which is not required by group I. Thus the expression library of group IV comprises vectors with different chemical and structural properties that the single plasmid of group I. Thus group I and IV are biologically, compositionally and biologically distinct and are capable of supporting individual patents.

The technical feature of group I, drawn to a plasmid wherein two restriction enzyme recognition sites into which a T-vector can be cloned are introduced at the downstream of a promoter of a vector that is constantly expressed at high levels regardless of the kind of a host cell, whereby the plasmid functions as both the T-vector and an expression vector, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganisms containing the expression vector, is distinct from the technical feature of group V, drawn to an expression vector library wherein the library of various genes is inserted in the pHCE-FOREX-T vector. The technical feature of group I does not require the pHCE-FORCEX vectors in the library of group V, and the vectors of group I can be used for alternate compositions, other than an library, such as to generate a transgenic animal,

as probe for an immunoblot, or for the production of a recombinant protein. The technical feature of group V, drawn to an expression library of pHCE-FORCEX vectors requires various target genes, which is not required by group I. Thus the expression library of group V comprises vectors with different chemical and structural properties that the single plasmid of group I. Thus group I and V are biologically, compositionally and biologically distinct and are capable of supporting individual patents.

The technical feature of group I, drawn to a plasmid wherein two restriction enzyme recognition sites into which a T-vector can be cloned are introduced at the downstream of a promoter of a vector that is constantly expressed at high levels regardless of the kind of a host cell, whereby the plasmid functions as both the T-vector and an expression vector, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganisms containing the expression vector, is distinct from the technical feature of group VI, drawn to a method of determining the cloning of a target genes, comprising the transformation of microorganisms with the libraries of claim 15. The technical feature of group I can be used in alternate methodologies, other than in a library, such as to generate a transgenic animal, as probe for an immunoblot, or for the production of a recombinant protein. The technical feature of group V, drawn to a method using an expression library of vector requires various target genes, which is not required by the vectors of group I. Thus the method of using an expression library of group VI comprises vectors with different chemical and structural properties that the single plasmid of group I. Thus group I and VI are biologically, compositionally and biologically distinct and are capable of supporting individual patents.

The technical feature of group II, drawn to a pHCE-FOREX plasmid functioning as bother a T-vector and an expression vector, wherein two AspEI restriction enzyme recognition sites are introduced at the downstream of the HCE promoter of the pHCE vector, and a polynucleotide having AspEI restriction enzyme recognition sites at its both ends is inserted between the two AspEI restriction enzyme recognition sites, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganisms containing the expression vector, is distinct from the technical feature of group III, drawn to methods of making a pHCE-FOREX plasmid function as both a T-vector and an expression vector. The composition of group II can be made using alternate methodologies and reagents that those in group III. Additionally, group II is drawn to a composition, and group III is drawn to a method of making a distinct composition that that of group II. Thus group II and III are biologically, compositionally and biologically distinct and are capable of supporting individual patents.

The technical feature of group II, drawn to a pHCE-FOREX plasmid functioning as bother a T-vector and an expression vector, wherein two AspEI restriction enzyme recognition sites are introduced at the downstream of the HCE promoter of the pHCE vector, and a polynucleotide having AspEI restriction enzyme recognition sites at its both ends is inserted between the two AspEI restriction enzyme recognition sites, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganisms containing the expression vector, is

distinct from the technical feature of group IV, drawn to an expression vector library, prepared by the method comprising the steps of: (a) removing the inserted polynucleotide by digesting the plasmid of claim 2 with the restriction enzyme selected from the group consisting of HphI, MboII, Asp EI, and XcmI; and (b) inserting the library of various genes into a position from which the polynucleotide was removed. The technical feature of group II does not require the library of group IV, and the vectors of group II can be used for alternate compositions, other than an library, such as to generate a transgenic animal, as probe for an immunoblot, or for the production of a recombinant protein. The technical feature of group IV, drawn to an expression library of vector requires various target genes, which is not required by group II. Thus the expression library of group VI comprises vectors with different chemical and structural properties that the single plasmid of group II. Thus group II and IV are biologically, compositionally and biologically distinct and are capable of supporting individual patents.

The technical feature of group II, drawn to a pHCE-FOREX plasmid functioning as bother a T-vector and an expression vector, wherein two AspEI restriction enzyme recognition sites are introduced at the downstream of the HCE promoter of the pHCE vector, and a polynucleotide having AspEI restriction enzyme recognition sites at its both ends is inserted between the two AspEI restriction enzyme recognition sites, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganisms containing the expression vector, is distinct from the technical feature of group V, drawn to an expression vector library wherein the library of various genes is inserted in the pHCE-FOREX-T vector. The technical feature of group II does not require the pHCE-FORCEX vectors in the library of group V, and the vectors of group II can be used for alternate compositions, other than an library, such as to generate a transgenic animal, as probe for an immunoblot, or for the production of a recombinant protein. The technical feature of group V, drawn to an expression library of pHCE-FORCEX vectors requires various target genes, which is not required by group II. Thus the expression library of group V comprises vectors with different chemical and structural properties that the single plasmid of group II. Thus group II and V are biologically, compositionally and biologically distinct and are capable of supporting individual patents.

The technical feature of group II, drawn to a pHCE-FOREX plasmid functioning as bother a T-vector and an expression vector, wherein two AspEI restriction enzyme recognition sites are introduced at the downstream of the HCE promoter of the pHCE vector, and a polynucleotide having AspEI restriction enzyme recognition sites at its both ends is inserted between the two AspEI restriction enzyme recognition sites, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganisms containing the expression vector, is distinct from the technical feature of group VI, drawn to a method of determining the cloning of a target genes, comprising the transformation of microorganisms with the libraries of claim 15. The technical feature of group II can be used in alternate methodologies, other than in a library, such as to generate a transgenic animal, as probe for an immunoblot, or for the production of a recombinant protein. The technical

feature of group V, drawn to a method using an expression library of vector requires various target genes, which is not required by the vectors of group II. Thus the method of using an expression library of group VI comprises vectors with different chemical and structural properties that the single plasmid of group II. Thus group II and VI are biologically, compositionally and biologically distinct and are capable of supporting individual patents.

The technical feature of group III, drawn to methods of making a pHCE-FOREX plasmid function as both a T-vector and an expression vector, is distinct from the technical feature of group IV, drawn to an expression vector library, prepared by the method comprising the steps of: (a) removing the inserted polynucleotide by digesting the plasmid of claim 2 with the restriction enzyme selected from the group consisting of HphI, MboII, Asp EI, and XcmI; and (b) inserting the library of various genes into a position from which the polynucleotide was removed. The technical feature of group III drawn to methods of making pHCE-FORCE vector does not require making the library of group IV. The technical feature of group IV, drawn to an expression library of vector requires various target genes, does not require making the pHCE-FORCE vectors and methodologies of group IV. Thus the expression library of group IV comprises vectors with different chemical and structural properties than the method of making the single plasmid of group III. Thus group III and IV are biologically, compositionally and biologically distinct and are capable of supporting individual patents.

The technical feature of group III, drawn to methods of making a pHCE-FOREX plasmid function as both a T-vector and an expression vector, is distinct from the technical feature of group V, drawn to an expression vector library wherein the library of various genes is inserted in the pHCE-FOREX-T vector. The technical feature of group III does not require the method steps of group V, and thus comprises separate reagents, compositions and resulting products. The technical feature of group V, drawn to an expression library of pHCE-FORCEX vectors requires various target genes, which is not required by the methodology of making the pHCE-FORCE vectors of group III. Thus the expression library of group V comprises vectors with different chemical and structural properties than the method of making the single plasmid of group III. Thus group III and V are biologically, compositionally and biologically distinct and are capable of supporting individual patents.

The technical feature of group III, drawn to methods of making a pHCE-FOREX plasmid function as both a T-vector and an expression vector, is distinct from the technical feature of group VI, drawn to a method of determining the cloning of a target gene, comprising the transformation of microorganisms with the libraries of claim 15. The technical feature of group III does not require the method steps of group VI, and thus comprises separate reagents, compositions and resulting products. The technical feature of group VI, drawn to a method using an expression library of vector requiring various target genes, which is not required by the methodology of making the pHCE-FORCE vectors of group III. Thus the method of using an expression library of group VI comprises vectors with different chemical and structural properties than the method of making the single plasmid of group III. Thus group III and VI are biologically,

compositionally and biologically distinct and are capable of supporting individual patents.

The technical feature of group IV, drawn to an expression vector library, prepared by the method comprising the steps of: (a) removing the inserted polynucleotide by digesting the plasmid of claim 2 with the restriction enzyme selected from the group consisting of HphI, MboII, Asp EI, and XcmI; and (b) inserting the library of various genes into a position from which the polynucleotide was removed, is distinct from the technical feature of group V, drawn to an expression vector library wherein the library of various genes is inserted in the pHCE-FOREX-T vector. The technical feature of group IV does not require 1) the method steps of group V, and thus comprises separate reagents, compositions and resulting products nor 2) the pHCE-vectors of group V. The technical feature of group V, drawn to an expression library of pHCE-FORCEX vectors does not result in the expression library of group IV. Thus the expression library of group V comprises vectors with different chemical and structural properties than the expression library of group IV. Thus group IV and V are biologically, compositionally and biologically distinct and are capable of supporting individual patents.

The technical feature of group IV, drawn to an expression vector library, prepared by the method comprising the steps of: (a) removing the inserted polynucleotide by digesting the plasmid of claim 2 with the restriction enzyme selected from the group consisting of HphI, MboII, Asp EI, and XcmI; and (b) inserting the library of various genes into a position from which the polynucleotide was removed, is distinct from the technical feature of group VI, drawn to a method of determining the cloning of a target gene, comprising the transformation of microorganisms with the libraries of claim 15. The technical feature of group IV does not require the method steps of group VI, and thus comprises separate reagents, compositions and resulting products. The technical feature of group VI, drawn to a method using an expression library of vector requiring various target genes, which is not required by the methodology of making the expression library of group IV. Thus the method of using an expression library of group VI comprises vectors with different chemical and structural properties than the method of making the expression library of group IV. Thus group IV and VI are biologically, compositionally and biologically distinct and are capable of supporting individual patents.

The technical feature of group V, drawn to an expression vector library wherein the library of various genes is inserted in the pHCE-FOREX-T vector, is distinct from the technical feature of group VI, drawn to a method of determining the cloning of a target gene, comprising the transformation of microorganisms with the libraries of claim 15. The technical feature of group V does not require the method steps of group VI, and thus comprises separate reagents, compositions and resulting products. The technical feature of group VI, drawn to a method using an expression library of vector requiring various target genes, which is not required by the methodology of making the expression library of group V. Thus the method of using an expression library of group VI comprises vectors with different chemical and structural properties than the method of making the expression library of group V. Thus group V and VI are biologically,

compositionally and biologically distinct and are capable of supporting individual patents.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE K. JOIKE whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K Joike, Ph.D./

Michele K Joike, Ph.D.
Examiner
Art Unit 1636